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(54) Prosthetic liner and method of making the liner with a prosthesis socket.

(57) A visco-elastic polymer liner (150) for use in donning over a residual limb (26) and fitting within the socket (146) of an artificial limb (140). The liner is shaped to have its cavity formed with a volume and shape less than a volume and shape of the residual limb for both tension and tissue configuration relief while the liner has an outer surface formed with a volume and shape greater than the volume and shape of the artificial limb socket for relief of certain tissue configurations and to create weight bearing, relief and compression areas on and in the liner to absorb and dissipate shock, shear and mechanical forces through the liner otherwise transmitted to the residual limb. The liner may have imbedded on its inner cavity side electrodes (152,154) adjacent muscles (38,40) that are sensitive to the muscle action potentials to generate signals to a power source to move an articulable artificial limb. The liner may take the shape of a tube to be donned over a paralyzed limb similarly having electrodes imbedded in its inner cavity side adjacent neuromuscular junctions which are connected to a muscle action potential generator to activate flexion and extension of the paralyzed limb. A method for making the liner is also claimed which comprises the making of a positive model of the residual limb, reducing the model, forming the liner about the reduced model and laminating a hard socket over a reduced model of the liner.

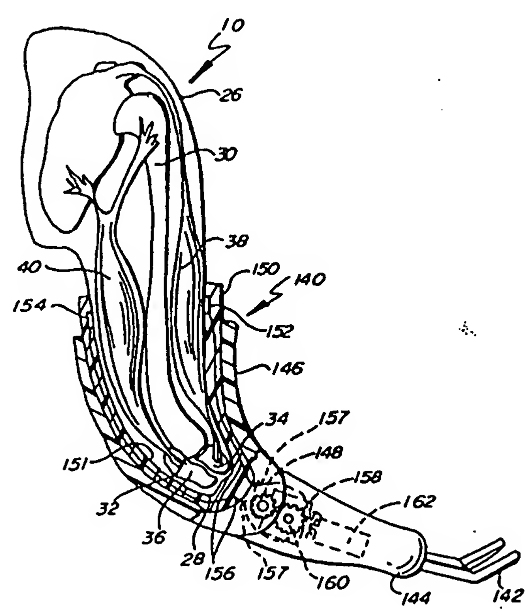

Fig.1B.

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BACKGROUND OF THE INVENTION

The present invention relates to prosthetic devices and more particularly to an improved liner for prosthetic devices including artificial limbs that also may be articulable or bionic.

An amputee is a person who has lost part of an extremity or limb such a leg or arm which commonly may be termed as a residual limb. Residual limbs come in various sizes and shapes with respect to the stump. That is, most new amputations are either slightly bulbous or cylindrical in shape while older amputations that may have had a lot of atrophy are generally more conical in shape. Residual limbs may further be characterized by their various individual problems or configurations including the volume and shape of a stump and possible scar, skin graft, bony prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations.

Referring to FIGS. 1 and 2, a below the knee residual limb 10 is shown and described as a leg 12 having been severed below the knee terminating in a stump 14. In this case, the residual limb 10 includes soft tissue as well as the femur 16, knee joint 18, and severed tibia 20 and fibula 22. Along these bone structures surrounded by soft tissue are nerve bundles and vascular routes which must be protected against external pressure to avoid neuromas, numbness and discomfort as well as other kinds of problems. A below the knee residual limb 10 has its stump 14 generally characterized as being a more bony structure while an above the knee residual limb may be characterized as including more soft tissue as well as the vascular routes and nerve bundles.

Referring to FIG. 3, amputees who have lost a part of their arm 26, which terminates in a stump 28 also may be characterized as having vascular routes, nerve bundles as well as soft and bony tissues. The residual limb 10 includes the humerus bone 30 which extends from below the shoulder to the elbow from which the radius 34 and ulna 36 bones may pivotally extend to the point of severance. Along the humerus bone 30 are the biceps muscle 38 and the triceps muscle 40 which still yet may be connected to the radius 34 and the ulna 36, respectively.

In some respects, the residual limb amputee that has a severed arm 26 does not have the pressure bearing considerations for an artificial limb but rather is concerned with having an artificial limb that is articulable to offer functions typical of a full arm, such as bending at the elbow and grasping capabilities. An individual who has a paralyzed limb would also have similar considerations wherein he or she would desire the paralyzed limb to have some degree of mobility and thus functionality.

Historically, artificial limbs typically used by a leg amputee were for the most part all mad out wood such an Upland Willow. The limbs were hand carved with sockets for receiving the stump 14 of the residual limb 10. Below the socket would be the shin portion with the foot below the shin. These wooden artificial limbs were covered with rawhide which often were painted. The sockets of most wood limbs were hollow as the limbs were typically supported in the artificial limb by the circumferential tissue adjacent the stump 14 rather than at the distil end of the stump 14.

Some artificial limbs in Europe were also made from forged pieces of metal that were hollow. Fiber artificial limbs were also used which were stretched around a mold afterwhich they were permitted to dry and cure. Again, these artificial limbs were hollow and pretty much supported the residual limb about the circumferential tissue adjacent the stump 14.

All of these various artificial limbs have sockets to put the amputee's stump 28 thereinto. There are generally two categories of sockets. There are hard sockets wherein the stump goes right into the socket actually touching the socket wall without any type of liner or stump sock. Another category of sockets is a socket that utilizes a liner or insert. Both categories of sockets typically were opened ended sockets were they had a hollow chamber in the bottom and no portion of the socket touched the distil end of the stump 14. So, the stump was supported about its circumferential sides as it fits against the inside wall of the sockets.

These types of sockets caused a lot of shear force on the stump 14 as well as had pressure or restriction problems on the nerve bundles and vascular flow of fluid by way of the circumferential pressure effect of the socket on the limb. This pressure effect could cause a swelling into the ends of the socket where an amputee may develop severe edema and draining nodules at the end of their stump 14.

With time, prosthetists learned that by filling in the socket's hollow chamber and encouraging a more total contact with the stump and the socket, the swelling and edema problems could be eliminated. However, the problematic tissue configurations, such as bony prominences, required special consideration such as the addition of soft or pliable materials to be put into the socket.

Today, most artificial limbs are constructed from thermoset plastics such as polyester resins, acrylic resins, polypropylenes and polyethylen s, which are perhaps laminated over a nylon stockinette which also may be impregnated by the various resins.

In the past, most artificial limbs were suspended from the amputee's body by some form of pulley, belt or strap suspension often used with various harnesses and perhaps leather lacers or lacings. Another method of suspending artificial limbs is known as the wedge suspension wherein an actual wedge is built into the socket which is more closed at its top opening. The wedge in the socket cups the medial femoral condyle or knuckle at the abductor tubical. Yet another form of suspension is referred to as the shuttle system or a mechanical hookup or linkup wherein a thin suction liner is donned over the stump that has a docking device on the distil end which mechanically links up with its cooperative part in the bottom of the socket chamber. Sleeve suspensions were also used wherein the amputee may use a latex rubber tube which forms into a rubber-like sleeve which would be rolled on over both the top of the artificial limb and onto the amputee's thigh. The sleeve suspensions have been used in combination with other forms of suspensions techniques.

The first artificial limb socket liners were made with molded horsehide leather covered with strips from extruded sheets of rubber glued to the leather as the liner was built up over a positive cast of the residual limb. As before, stump socks typically made of cotton or wool were used with these first liners as well as with the earlier hard sockets.

The next major socket liner was formed from an expanded foam such as polyurethane foam as sold by Durr-Fillauer Medical, Inc. of Chatanooga, Tennessee. After a positive cast was made of the residual limb, a cone-like structure of the hard foam plastic was formed and heated. Next, the expanded foam was pulled over the cast of the residual limb in an effort to form it to the limb after which the foam was cooled and its shape was retained over the positive cast. Thereafter, a hard shell socket could be built or laminated over the liner from which a shin and foot of the artificial limb could be attached.

Another type of socket liner was made from a combination of silicone and gauze being sandwiched in between two pieces of leather. However, this type of liner had problems in that it was much too rigid, wouldn't stretch and eventually loosened up and migrated thereby becoming ineffective.

The next group of socket liners were made from the impregnation of a cotton stockinette with silicone resins formed over a positive cast of the residual limb. The problem with these types of liners is that the silicone could not migrate or stretch and was often short lived in that sweat from the residual limb would break down the silicone and create pungent and unsanitary conditions.

Another type of silicone liner without the impregnated stockinette has been utilized to create suction about the residual limb for use in combination with perhaps a shuttle or mechanical link up device with the socket. However, these types of liners offered no yield or cushion and required the wearing of stump socks.

While some of these devices addressed some of the problems associated with prosthetics, none of the artificial limbs, liners and sockets, individually or in combination offered a prosthesis that presented a total contact relationship with the residual limb; absorbed and dissipated shear, shock and mechanical forces transmitted to the limb tissues by the artificial limb; controlled perspiration of the residual limb; controlled residual limb volume; and, promoted equal weight distribution while having a long life expectancy.

There is a need for a liner to be used with prosthetic devices that will offer total contact relationship with the residual limb; provide hypoberic suction suspension with a sticky or tacky surface condition; absorb and dissipate shock, mechanical and shear forces typically associated with ambulation, twisting and turning and weight bearing with an artificial limb; control perspiration; control residual limb volume by way of even weight distribution; and offer relief for the various tissue configurations that plague residual limbs while yet being of long life.

SUMMARY OF THE INVENTION

A visco-elastic polymer liner for use in donning over a residual limb and fitting within the socket of an artificial limb. The liner is shaped to have its cavity formed with a volume and shape less than a volume and shape of the residual limb for both tension and tissue configuration relief while the liner has an outer surface formed with a volume and shape greater than the volume and shape of the artificial limb socket for relief of certain tissue configurations and to create weight bearing, relief and compression areas on and in the liner to absorb and dissipate shock, shear and mechanical forces through the liner otherwise transmitted to the residual limb. The liner may have imbedded on its inner cavity side electrodes adjacent muscles that are sensitive to the muscle action potentials to generate signals to a power source to move an articulable artificial limb. The liner may take the shape of a tube to be donned over a paralyzed limb similarly having electrodes imbedded in its inner cavity side adjacent neuromuscular junctions which are connected to a muscle action potential generator to activate flexion and extension of the paralyzed limb. A method for making the liner is also claimed which comprises the making of a positive model of the residual limb, reducing the model, forming the liner about the reduced model

and laminating a hard socket over a reduced model of the liner.

A principal object and advantage of the present liner is that it provides total environment control about the tissue of the residual or paralyzed limb by way of a total contact relationship between the liner and the tissue.

Another advantage and object of the present invention is that it has a tacky or sticky surface which permits the liner to actually tack up to the limb tissue and provide a hypoberic suction when used as a socket liner which eliminates a bulky suspension apparatus as well as control on the residual limb volume and perspiration.

Another object and advantage of the present invention is that the liner, when utilized with an artificial limb socket, totally absorbs and dissipates shock, shear and mechanical forces which are normally transmitted directly to the tissues of the residual limb from the artificial limb during weight bearing, ambulation, twisting and turning.

Another advantage and object of the present invention is that the total contact relationship between the residual limb tissues, the liner and the artificial limb socket permits equal weight distribution resulting in lower pounds per square inch pressure on limb tissues thereby permitted extended comfortable wear of an artificial limb heretofore not known.

Another advantage and object of the present invention is that the visco-elastic, energy absorbing, flexible polymer liner will stretch, move or creep internally while having a memory for the liner to return to its original shape.

Another advantage and object of the present invention is that the liner when used with a socket and artificial limb may be used with any means of suspension although suction socket with a mechanical link-up appears advantageous.

Another principal object and advantage of the present liner is that the polyurethane elastomer material permits additional buildup and removal of material for adjustment of the liner over time that is easy and simple without the need of additional catalysts.

Yet another advantage and object of the present invention is that the liner is durable for long wear and is readily cleanable with soap and water to provide an odor free clean environment for a residual limb or a paralyzed limb.

A final principal object and advantage of the present invention is that an amputee with a residual limb may simply don the liner and place the limb within a socket without the need of additional padding or stump socks which has normally been the case until this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of the tissue and skeletal structure of an amputee's residual limb;

FIG. 2 is a front elevational view of a residual limb with a volumme and shape and the skeletal structure visible while donning a light cotton marking sock;

FIG. 3 is a side elevational view of a residual limb in the form of an amputated arm showing the skeletal and muscular structure of the residual limb;

FIG. 4 is a front elevational view of a plaster wrap or cast of the residual limb of FIG. 2 constituting a negative model of the residual limb;

FIG. 5 is a front elevational view of a plaster positive model of the residual limb of FIG. 2 made from the mold of FIG. 4;

FIG. 6 is a reduced positive model of the residual limb of FIG. 2 formed by reduction of the positive model of FIG. 5 having a volume and shape less than that of the positive model;

FIG. 7 is a front elevational view of the reduced positive model or prototype of FIG. 6 mounted in a jig with a liner filler medium stretched thereover;

FIG. 8 is a cross-section take along lines 8-8 of FIG. 7;

FIG. 9 is a front elevational view of the reduced positive model of the residual limb with a second plaster wrap over the filler medium and reduced positive model of the limb as shown in FIG. 7;

FIG. 10 is a cross sectional view taken along lines 10-10 of FIG. 9;

FIG. 11 is an elevational view of the jig for keying the second plaster wrap of FIG. 9 about the reduced positive model of the residual limb of FIG. 6 with the base of the jig partially broken away;

FIG. 12 is a front elevational view of the residual limb donning the liner of the present invention with a light cotton marking sock thereover;

FIG. 13 is a front elevational view of the residual limb with liner and cotton sock of FIG. 12 having a third plaster wrap thereover which is a negative model of the socket;

FIG. 14 is a plaster cast or positive model of the socket made from the plaster wrap of FIG. 13;

FIG. 15 is a reduced positive model of the socket made from the model of FIG. 14 having a volume and shape less than that of the positive model of FIG. 14;

FIG. 16 is a side elevational view of the socket and remaining parts of an artificial limb laminated or built about the reduced positive model

socket of FIG. 15;.

FIG. 17 is an elevational view of a mechanical link-up, hook-up or interlocking linkage for securing the residual limb liner to an artificial limb;

FIG. 18 is a side elevational view of an amputee's residual limb donning a bionic or articulable limb partially broken away in an extension position;

FIG. 19 is the residual limb and artificial limb of the FIG. 18 in its flexion position; and

FIG. 20 is an elevational view of a paralyzed upper limb or arm donning a bionic harness for actuating paralyzed muscle movement.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1-5, normally amputees are seen by the prosthetist post operatively after they have had primary wound healing. While the residual limb 12 consists of either a leg 12 or an arm 26, the amputees are evaluated for the size and shape of their stump 14 or 28 with additional considerations given to scar, skin graft, bony prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations. Through conversations, the amputees are also evaluated as to what their activity levels are.

Next, a single ply thin cotton casting sock 42 is then placed over the residual limb 10. Certain tissue configuration locations as well as pressure sensitive areas are then marked with indelible ink 45 on the casting sock 42. Next an orthopedic plaster wrap 44 that has been dipped in water is formed about the residual limb. After the wrap has been permitted to set and harden, the residual limb 10 is withdrawn from the plaster wrap 44 leaving the casting sock 42 adhered to the plaster wrap. Various separating or releasing media may be used on the residual limb before donning of the casting sock 42, such as a baby powder, vaseline or petroleum jelly, which assists in the removal of the residual limb from the plaster wrap which constitutes the first negative mold of the residual limb 10.

The plaster wrap 44 or first negative mold of the residual limb 10 is next filled with plaster, such as dental plaster, and a centrally located mandrel or pipe 48 is positioned within the plaster cast for later key positioning within a jig or for simply supporting the plaster cast 46 after it is removed from the plaster wrap 46. Again, known separating agents may be used between the plaster wrap 44 and the plaster cast 46.

The plaster cast 46, once removed from the plaster wrap 44, constitutes the original prototype and first positive model 46 of the residual limb 10. As can be seen in the original prototype 46 in FIG. 5, the ink marks 43 readily transfer over to the plaster cast 46 for consideration of the residual limb's volume and shape, category and tissue configurations, such as a scar, skin graft, bony prominence, uneven limb volume, neuroma, edema, pain, pressure sensitive areas and soft tissue. Certain of these areas will require the liner 90 to have varying degrees of thickness and density to accommodate these considerations.

Thus, referring to FIG. 6, the original prototype 46 of FIG. 5 is reduced or built up to form the reduced positive model of the residual limb 50. The reduction of this positive model will result in a tension factor on the liner 90 when it is stretched and donned by the residual limb 10, which is a little larger than the volume and shape of the inner cavity 91 of liner 90, as will become clear.

Applicant presently contemplates that computer controlled mills will assist the prosthetists in either shaving off or melting off in a more accurate fashion portions of the original prototype 46 to create the reduced positive model 50 of the residual limb 10.

It is important that the reduced positive model not be reduced in size too much as to create a shear force upon the tissues of the residual limb 10 creating problems.

The prosthetist must next consider what thickness he or she wishes the liner 90 to have. Normally the liner 90 is between five-eights to three-quarters of an inch thick at the stump end 14 and roughly about three-sixteenths to a quarter of an inch thick around the entire residual limb. Additional considerations would include making the liner thinner where specific weight bearing areas of the residual limb would be located as well as making certain areas of the liner 90 thicker to displace and compress the liner 90 in a manner to disperse pressure away from certain tissue configurations. It is also known that where a person is more fleshy, such as in the femur 16 area in the above the knee amputation, the liner 90 would have generally thinner dimensions to add weight bearing areas to the soft tissues. Where there exists a bony prominence, such as in the below the knee amputee, the liner 90 may be a little thicker to disperse the weight bearing areas.

With these considerations in mind, the prosthetists takes the reduced positive model 50 with its mandrel 48 and mounts the model 50 in jig 53 suitably upside down for ease of working as seen in FIG. 7. Thereafter, a filler medium, such a thermoplastic foam 52, is then built on and about the reduced positive model 50 which actually represents the thickness of the liner 90 to be made. The filler medium 52 may be a wool stump sock or various types of expanded thermoplastic foams will also work well. The thermoplastic foams 52 can be

readily formed into the shape of a cone and heated. Thereafter, the heated foam 52, which becomes flexible is formed over the reduced positive model 50 and perhaps vacuumed thereto by way of an evacuated plastic bag being placed over the thermoplastic foam 52. Sheets of the foam 52 that are formed into cone-like structures are available from previously mentioned Durr-Fillauer Medical, Inc. of Tennessee.

As stated, the expanded thermoplastic foam, such as a polyurethane foam or other such expanded foam products such as polyethylene or polypropylene, represents the space where the liner 90 will be. Thus, additional pieces of the foam 52 may be added to the reduced positive model 50, such as the distal end of the stump 14 to form a distal end cap as well as or other areas which may require additional thicknesses due to tissue configurations.

After a releasing or separating medium has been applied to the thermoplastic foam 52, a second plaster wrap 54 is applied over the foam 52 thereby creating a second enlarged negative mold 54 as shown in FIGS. 9 and 10. Thus, the reduced positive model 50 of the residual limb 10 is in a predetermined spaced relationship with the second plaster wrap 54 by way of the thermoplastic foam interface 52.

Referring to FIG. 11, the second plaster wrap 54 has an adaptor block 60, suitably made of wood or foam, affixed to its bottom such as by glue.

The block 60 appropriately has a threaded aperture 62 through which a wing nut screw 64 rotatably may pass. The plaster wrap 54 with its adapter block 6 is now ready for placement within the transfer jig 70. Transfer jig 70, as shown in FIG.7, is a memory device for repeatedly keying the reduced positive model 50 and the second plaster wrap 54 should additional liners 90 be required to be built over time. Transfer jig 70 includes a horizontal plate 72 with keying connectors or ridges 74 which will permit indexing the adaptor block 60 therein for repeated and exact placement of the second plaster wrap 54 upon the transfer jig 70.

Transfer jig 70 also includes a calibrated vertical support 76 having a first collar 78 which adjusts vertically and horizontally and may be secured with respect to those two planes by collar fastener 80. First collar 78 and second collar fastener 82 support, hold and key a horizontal extension 84 which has a second horizontal collar 86 located at its opposing end. The second collar 86 similarly has a collar fastener 88 for locking the collar 86 about mandrel 48.

By this arrangement, reduced positive model 50 of residual limb 10 and the second plaster wrap 54, which is the negative mold of the socket may be keyed together repeatedly in the exact relationship so that the liner 90 may be repeatedly poured and shaped into the same shape.

With the thermoplastic foam 52 removed from between the reduced positive model 50 and the second plaster wrap 54, the liner 90 in its liquid and moldable form may be introduced into the enlarged negative mold 54. However, the liquid may first be subjected to vacuum, such as in a desiccator, to draw out excess gases and bubbles. Urethane liner 90 is suitably made from a visco-elastic polymer which is energy absorbing and flexible exhibiting a flowability or internal movement character with recovery of shape or memory. Applicant has found that a polyurethane elastomer is suitably appropriate in that it is further washable, durable, bacterialstatic and fungistatic. Urethanes are technically called a carbamate ester which is made from a combination of isocyanates and alcohols. More definitively, applicant has found that an aromatic diisocyanate and elastisizing polyols, such as diols or triols, form suitably urethanes or polyurethanes.

Applicant has found that a preferable polyurethane includes the combination of an antioxydant with free toluene diisocyanate and a blend of polyether polyols with bismuth carboxylate. These components are commercially available from Rieckens Orthodics Laboratories of 401 North Green River Road, Evansville, Indiana 47715 and has been used in the past as sole material or inlay for use with shoes. Although energy absorbing polymers have been used as sole or inlays for shoes, they have never been utilized in the context of the present invention or prosthetic.

Applicant has also found that vinyl resins or moldable thermoplastics exhibiting visco-elastic polymer qualities, energy absorption, flexibility, flowability and recovery also will work in forming liner 90.

Once the diiosocyanate and polyols components have been mixed together forming viscous fluid with the appropriate and predetermined durometer, the fluid is poured into the second plaster wrap 54. The reduced positive model 50 of the residual limb 10 is then placed into the second plaster wrap 54 and keyed into the transfer jib 70 as if thermoplastic foam 52 was still interfaced between the model 50 and the wrap 54. A releasing agent, such as a silicone base mold separator, may be utilized between the wrap 54 and the model 50 so that the liner 90 will readily separate after be permitted to set and cure after one or two hours. Separators are also available from Riechens Orthodic Laboratories.

Referring to FIGS. 12-16, the prosethistist next has the amputee don the urethane liner 90 over his or her residual limb 10 after the urethane liner 90

has been cleaned up and washed with soap. If the polyurethane liner 90 is of extensive length, the amputee may need a wetting agent such as a petroleum jelly which will readily dissipate. Otherwise, the liner 90 is slid or rolled onto the amputee's residual limb 10. Should the liner 90 require some build up, hte freshly mixed components will readily adhere to the liner 90.

Thereafter, another single ply thin cotton casting sock 93 is then placed over the liner 90 which is marked with the indelible ink 94 for a second consideration of certain previously mentioned tissue configurations such as bony prominences, pressure areas and scar problems. This step is necessary because once the liner 90 is donned over the residual limb 10 with some degree of tension, some of the relief, shape and volume adjustments previously made become dissipated.

Thereafter, a third plaster wrap 96 or a negative model of the artificial limb socket 104 is then made about the residual limb 10 with the liner 90 and marked up casting sock 93 thereon.

After the third plaster wrap 96 has cured and the residual limb 10, liner 90 have been removed from the third plaster wrap 96 or negative model of the socket, a plaster cast or positive model of the socket 98 is made from dental plaster. Suitably a mandrel 100 is placed in the plaster 98 to assist in construction of the socket 104. As seen in FIG. 14, a positive model of the socket 98 has the ink marks 94 for certain reduction and build up considerations for various tissue configurations and so on.

Next, the positive model of the socket 98 is milled or shaved to create a reduced positive model of the socket 102 which is necessary to create weight bearing areas and compression upon the liner against the inner cavity 91 of the liner 90 on the residual limb and upon the outer surface 92 of the liner 90 upon the socket 104.

Referring specifically to FIG. 16, the artificial limb 110 includes its socket 104, shin 106 and foot 108. The limb 110 may be constructed by way of polyester or acrylic resins laminated over nylon stockinettes or by way of thermoset plastics including polypropylene and polyethylene. The artificial limb 110 may use various suspension techniques as mentioned. Once the socket 104 has been formed by lamination over the reduced positive model of the socket 102, the artificial limb 110 is most suitable for total contact hypoberic suction shuttle suspension as shown in FIG. 17. By this arrangement, the liner 122 is donned by the artificial limb and placed within socket 124. A releasably mechanical interlocking hookup or linkage 126 includes a ring 128 supported by a mounting means in the liner and a pin 130 mounted in the socket adjacent the shin. As previously stated, a sleeve 132 may also be placed over the artificial limb 120 and the leg 10.

The visco-elastic, energy absorbing, flexible polymer liner of the present invention has applications beyond that of merely being a total contact hypoberic suction, equal weight distribution socket liner. That is, the polyurethane liner, which readily tacks up to the skin of the human body to the point of almost actually becoming part of the skin readily permits the proper location of electrodes for use and application of bionic artificial limbs or the application of creating movement of paralyzed limbs.

Referring to FIGS. 18 and 19, the application of the present invention in a bionic artificial limb or arm 140 will be explained. The amputee's arm 26 consists of a stump 28 below the elbow 32 wherein the radius 34 and ulna 36 bones have been severed. The amputee has normal and innervated bicep and tricep muscles 38 and 40 along the humerus with the exception that their lower most connection to the radius and ulna, which have been severed, provide no lever for these muscles to permit a function.

Consequently, a bionic or articulable artificial arm 140, as is known, typically would have a moveable hook or hand 142 and a pivotally mounted motor driven forearm 144 connected to the above elbow socket section 146. The socket section 146 has a pivot gear 148. The polyurethane liner 150 of the present invention includes an inner cavity 151 which has a biceps electrode 152 and a triceps electrode 154. The electrodes 152 and 154 touch the skin and lie over the muscles 38 and 40 in a predetermined location to monitor muscle action potential. The electrodes 152 and 154 are then wired 156 through the liner 150 to touch plates 157 which are further wired into the bionic arm 140. Signals from the electrodes 152 and 154, which sense muscle action potentials, are amplified and relayed to a forearm 144 control motor 158 which operates gear 160, all of which are powered by battery 162.

In operation, the amputee consciously flexes his biceps muscle 38. The muscle action potential is then sensed by bicep electrode 152 after which it is relayed and amplified to engage motor 158 and gear 160 to drive the forearm portion 144 of bionic arm to a flexion motion. When the amputee wishes to have the forearm 144 move into an extension or downward motion, the amputee simply flexes his or her tricep muscles 40. The muscle action potential is then sensed by triceps electrode 154 which similarly engages motor 158 and gear 160 in reverse operation to move the forearm 144 downwardly.

The liner 150 of the present invention permits this operation with repeated accuracy due to the liners construction, location of the electrodes 152 and 154 and wires 157 within the liner by way of

forming the liner as previously stated. The exact construction and donning of the liner 150 will assure that electrodes 152 and 154 are repeatedly placed over the proper location on the amputee's skin and wires 156 will engage or touch plates 157.

Referring to FIG. 20, the liner of the present invention has application for individuals who have a paralyzed limb 170 wherein the paralysis is due to a disconnection along the nerve pathways between the brain and the muscle. In other words, the muscles 38 and 40, once properly stimulated, will permit flexion and extension of the paralyzed individuals's forearm.

Initially the proper locations to stimulate the bicep and tricep muscles 38 and 40 must be predetermined by known means, such as a "Tens device." Thereafter, a polyurethane liner or tube 172 is formed as previously disclosed herein having an inner wall 73. The bicep and tricep electrodes and 174 and 176 are then placed within the liner during its formation with connection wires 178. Wires 178 are connected to a bionic harness 179 as shown. The electrodes 174 and 176 are connected by way of the wires 178 to a muscle action potential generator 180 which receives signals from amplifier 184 and limb flexion or extension signal receiver 186, all of which are powered by battery 182. When a flexion or extension signal is received by the receiver 186, a muscle action potential is discharged at the electrodes 174 or 176 likely located near a neuromuscular junction which will initiate either flexion or extension.

Again, it is the unique method of construction and materials from which the present liner is made which permits exact location of electrodes on a repeated basis on an individual's skins together with the tacking up of the liner upon the skin no matter what the individual's position or activity level that permits the liner to be readily applicable to bionics or robotics.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof; therefore, the illustrated embodiment should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

Claims

1. A socket liner for an amputee that has a residual limb characterized as having a stump, a volume and shape and possible scar, skin graft, boney prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations and wherein the amputee utilizes an artificial limb having a socket for receiving the stump and part of the limb, the liner comprising a polyurethane lastomer formed from adding together predetermined amounts of isocyanates and alcohols.

2. The socket liner of claim 1, wherein the liner has a cavity formed with a volume and shape less than the volume and shape of the residual limb with relief for certain configurations to tension the liner over the residual limb into a total contact relationship when donned by the amputee.

3. The liner of claim 2, wherein the socket has a volume and shape larger than the volume and shape of the residual limb and wherein the liner has an outer surface formed with a volume and shape greater than the volume and shape of the socket to create a compression upon the liner when donned onto the residual limb and placed into the socket.

4. The liner of claim 1, wherein the polyurethane elastomer is made from adding together predetermined amounts of a diisocyanate and polyether polyols.

5. The liner of claim 1, wherein the polyurethane elastomer is made from adding together predetermined amounts of an antioxidant with free toluene diisocyanate and a blend of polyether polyols with bismuth carboxylate.

6. The liner of claim 1, further comprising a mechanical interlocking linage releasably connecting the liner and the artificial limb.

7. The liner of claim 2, wherein the residual limb is further characterized as having contractable muscles which still generate action potentials that no longer move an articulated segment of the limb due to amputation of that segment of the limb and wherein the artificial limb is articulable and moved by a power source, the liner has electrodes imbedded in the cavity adjacent such muscles that sense the muscle action potential and generate signals to the power source to move the articulable artificial limb.

8. An improved prosthesis for an amputee that has a residual limb characterized by a leg with a stump, a volume and shape and possible scar, skin graft, boney prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations wherein the prosthesis comprises:

a) an artificial limb having a socket conforming to a volume and shape larger than the volume and shape of the residual limb with relief for certain configurations; and
b) a visco-elastic, energy absorbing, flexible polymer liner for donning over the residual limb and fitting into the socket having:
i) a cavity formed with a volume and shape less than the volume and shape of the residual limb with relief for certain configurations to tension the liner over the residual limb into a total contact relationship when donned; and
ii) an outer surface formed with a volume and shape greater than the volume and shape of the socket with relief for certain configurations to create weight bearing, relief and compression areas on and in the liner to absorb and dissipate shock, shear and mechanical forces to the liner otherwise transmitted to the residual limb.

9. The improved prosthesis of claim 8, wherein the liner is a polyurethane elastomer.

10. The improved prosthesis of claim 9, wherein the polyurethane elastomer is made from adding together predetermined amounts of a diisocyanate and polyether polyols.

11. The improved prosthesis of claim 9, wherein the polyurethane elastomer is made from adding together predetermined amounts of an antioxidant with free toluene diisocyanate and a blend of polyether polyols with bismuth carboxylate.

12. The improved prosthesis of claim 8, further comprising a mechanical interlocking linkage releasably connecting the liner and the artificial limb.

13. The improved prosthesis of claim 8, wherein the liner is a vinyl resin.

14. Method for making an improved liver and socket for an amputee that has a residual limb characterized as having a stump, a volume and shape and possible scar, skin graft, boney prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations, the method comprising:
a) constructing a first negative mold of the residual limb;
b) constructing a positive model of the residual limb from the residual limb negative mold;
c) reducing and building up the positive model for relief of certain tissue configurations;
d) placing a filler medium over the reduced positive model;
e) constructing a second negative mold of the reduced positive model with a filler medium thereon;
f) removing the filler medium; introducing a visco-elastic, energy absorbing, flexible polymer liner between the reduced positive model and the second negative mold;
g) removing the second negative mold from the liner;
h) reducing and building up the liner for relief of certain tissue configurations;
i) constructing a third negative mold of the socket;
j) constructing a positive model of the socket;
k) reducing and building up the positive model of the socket to create weight bearing, compression and relief areas on the liner; and
l) constructing the socket over the reduced and built up positive model of the socket.

15. A liner for a prosthetic device for a person with a paralyzed limb due to a nerve pathway blockage, the limb further characterized as having normal neuromuscular functions and muscles, and a volume and shape wherein the prosthetic device has a limb flexion and extension signal receiver connected to an amplifier which is connected to a muscle action potential generator, the liner comprising: a tube made of a visco-elastic polymer having an inner wall defining a cavity formed with a volume and shape less than the volume and shape of limb to tension the liner over the limb into a total contact relationship when donned, the liner has electrodes imbedded in the cavity adjacent neuromuscular junctions which are connected to the muscle action potential generator to activate flexion and extension of the paralyzed limb.

16. The liner of claim 15, wherein the visco-elastic polymer is a polyurethane elastomer.

17. The liner of claim 16, wherein the polyurethane elastomer is made from adding together predetermined amounts of a diisocyanate and polyether polyols.

18. The liner of claim 16, wherein the polyurethane elastomer is made from adding together predetermined amount of an antioxidant with free

toluene diisocyanate and a blend of polyether polyols with bismuth carobylate.

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 40 2662

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US-A-3 377 416 (KANDEL) * column 1, line 61 - column 2, line 47; claims 1,7; figures * ---	1,8,14	A61F2/80 A61F2/72
A	US-A-3 393 407 (KANDEL) * the whole document * ---	1,8,14	
A	US-A-2 671 225 (SCHOENE ET AL.) * claim 1; figures * ---	1,8	
A	FR-A-1 532 625 (ROYER) * the whole document * ---	1,8,14	
A	EP-A-0 261 884 (NATIONAL RESEARCH DEVELOPMENT CORP.) * abstract; figure 6 * * column 1, line 28 - line 46 * * column 2, line 30 - column 3, line 7 * ---	1,8,14	
A	EP-A-0 057 839 (BAYER AG) * the whole document * ---	1,4	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US-A-3 631 542 (POTTER) * abstract; figures 1,5 * ---	15	A61F A61L
A	US-A-3 557 387 (OHLENBUSCH ET AL.) * figures 1,11 * -----	15	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	31 March 1994	Kanal, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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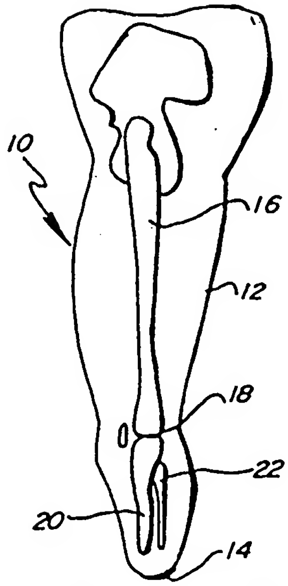

Fig.1.

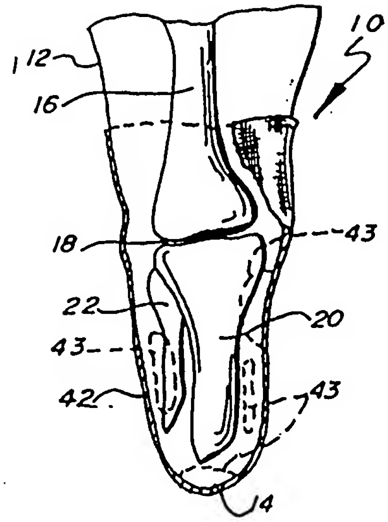

Fig.2.

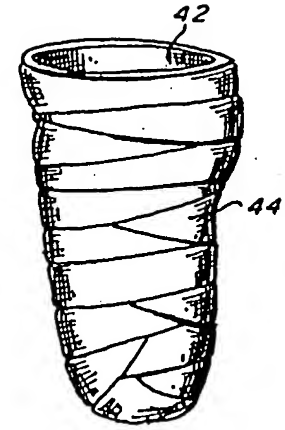

Fig.4.

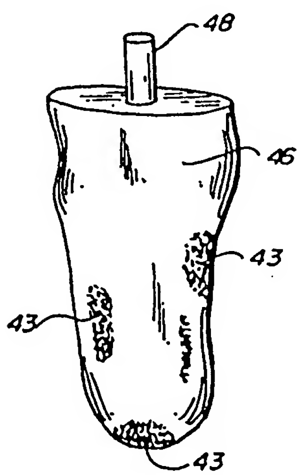

Fig.5

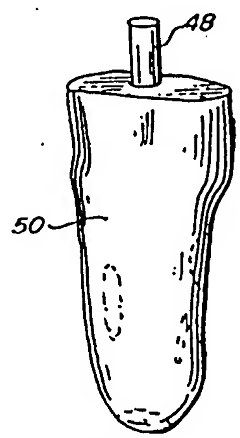

Fig.6.

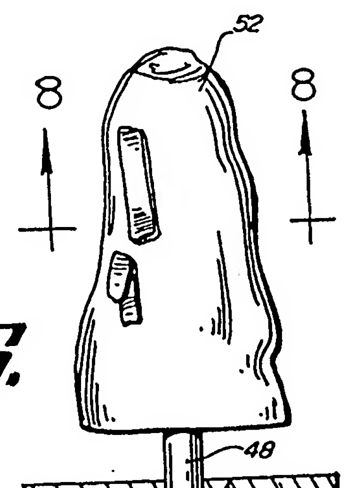

Fig.7.

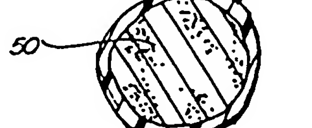

Fig.8

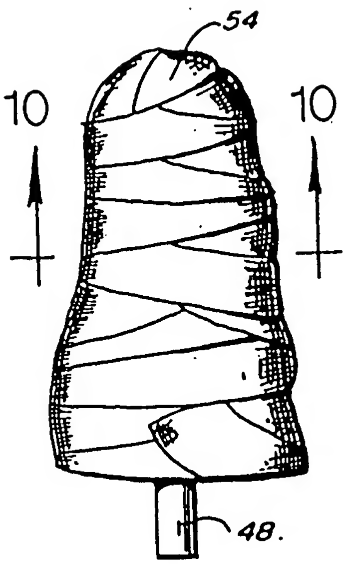

Fig. 9.

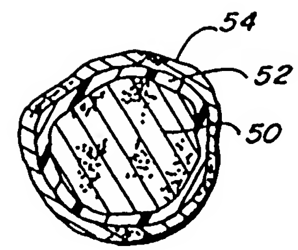

Fig. 10.

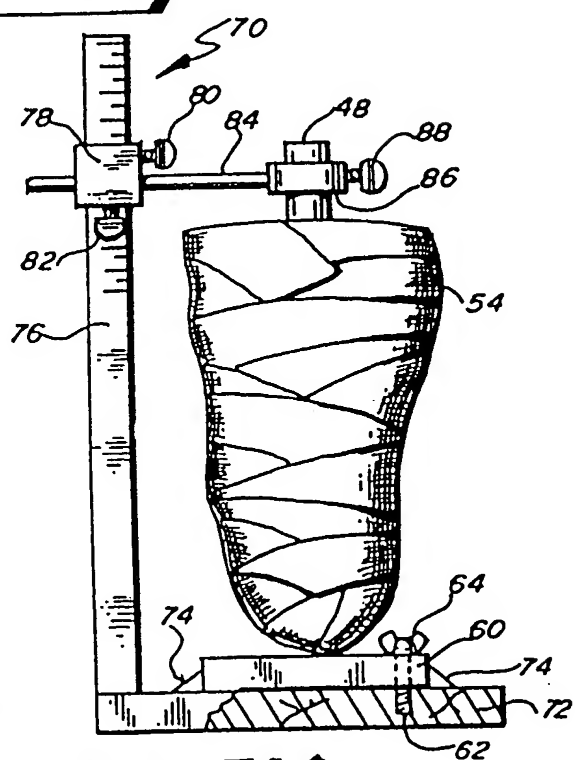

Fig. 11.

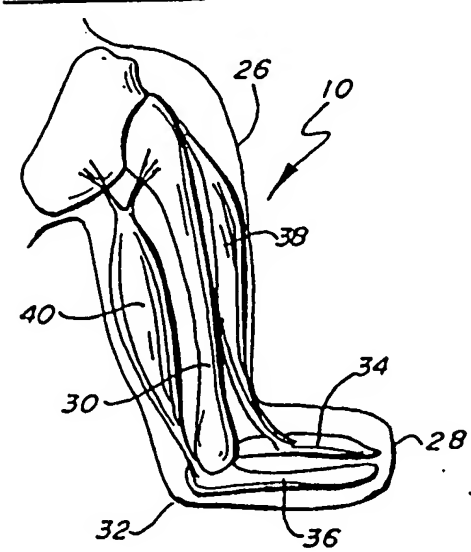

Fig. 3.

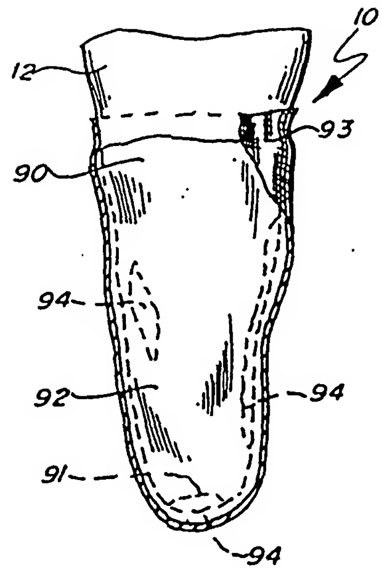

Fig.12.

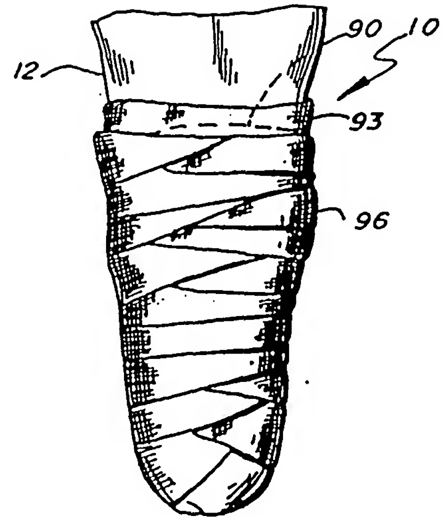

Fig.13.

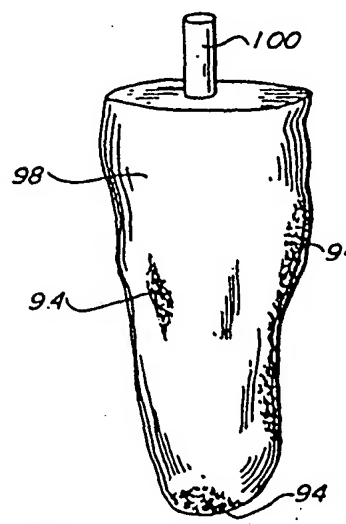

Fig.14.

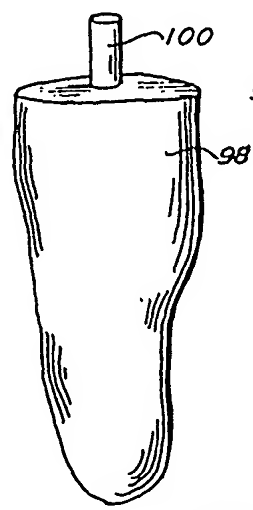

Fig.15.

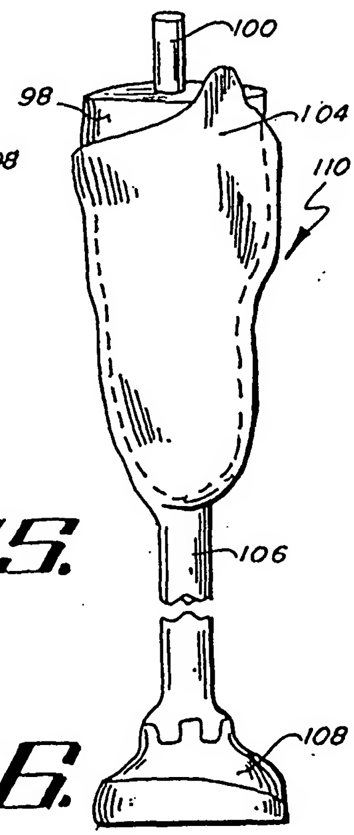

Fig.16.

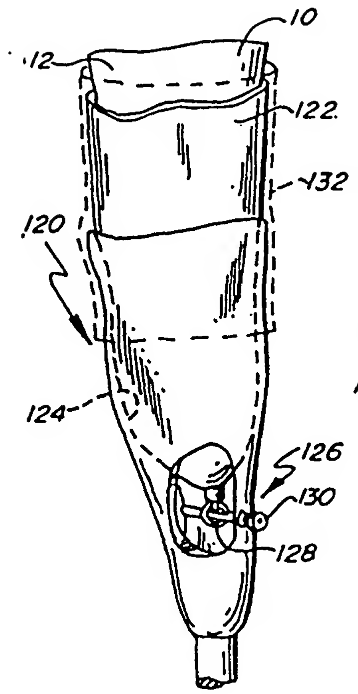

Fig.17.

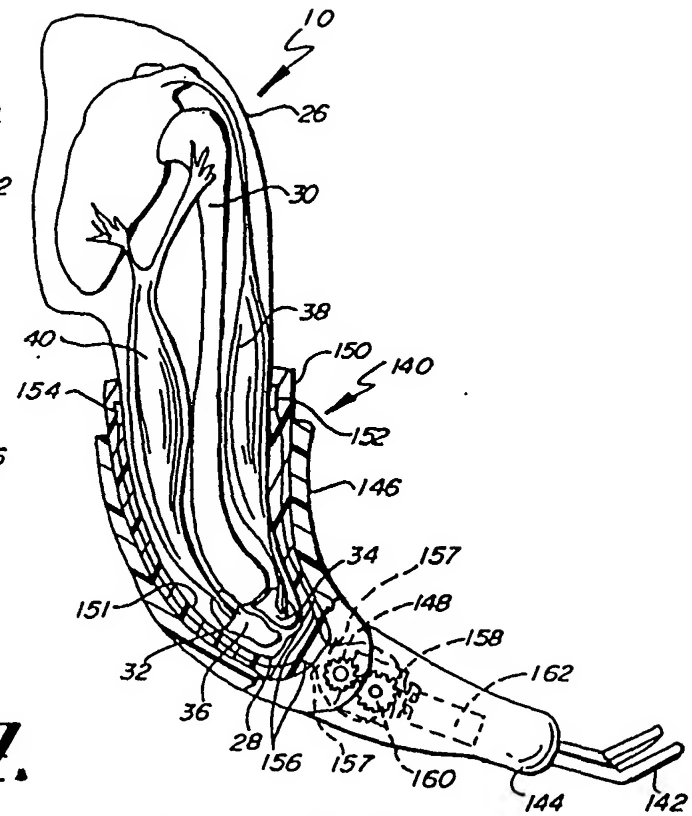

Fig.18.

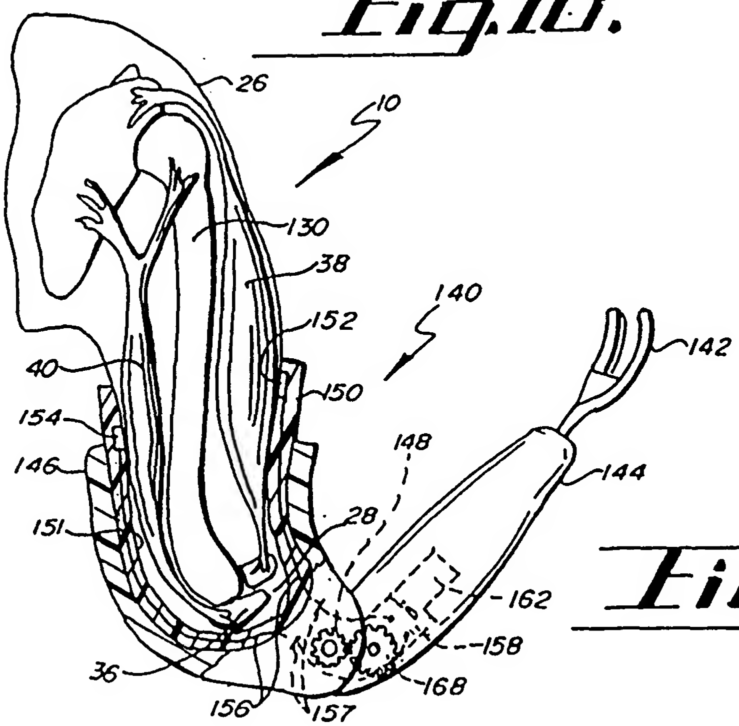

Fig.19.

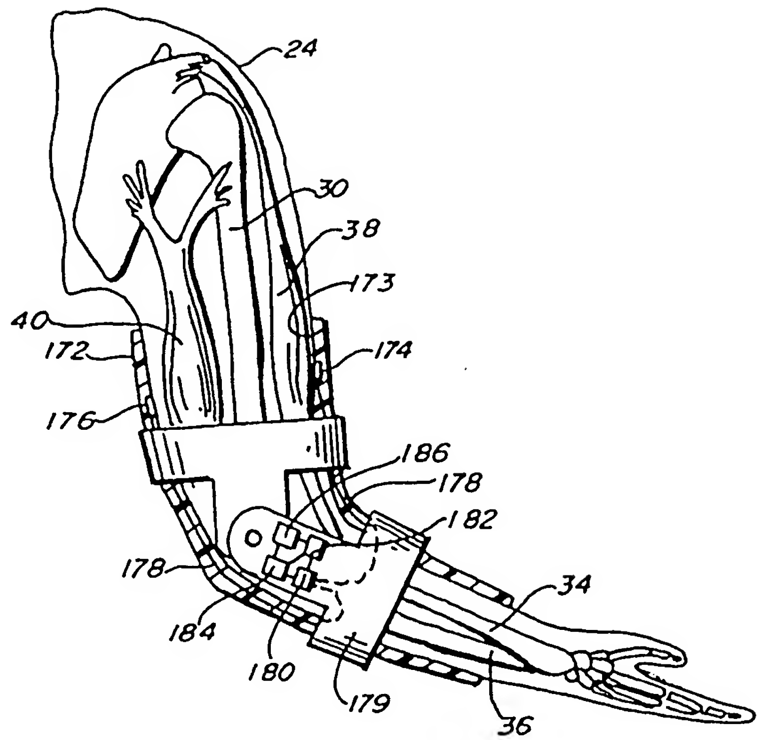

Fig.20.

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(54) **Limb prosthesis production and material therefor.**

(57) A method of making a limb prosthesis for an amputee patient comprises rectifying the relevant limb stump (20) by the application thereto of at least one moulding (16,17,18) of viscoelastic material precast to a predetermined shape, taking an impression (30) of the rectified stump, and using the impression to determine the shape of a stump-receiving cup in the prosthesis. The impression is suitably taken by wrap casting around the rectified stump, and the cup shape determined by casting a replica (31,32) in the wrap cast as a mould, to allow formation of the cup on the replica. Mouldings for this method are suitably provided as an assembly on a common support (10) having discrete depressed zones (13,14,15) in which appropriate material is cast for use in the production of a particular form of prosthesis. An assembly for a leg prosthesis of patella borne form suitably comprises two disc mouldings (17,18) to cover the tibial condylar protuberances and a strip moulding to cover the front of the tibia.

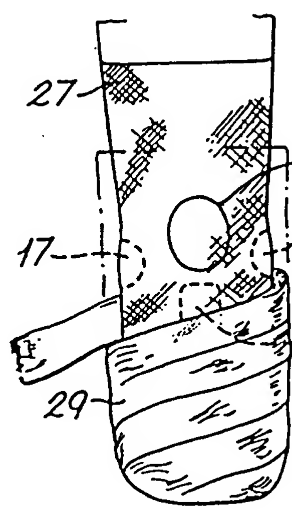

Fig. 6

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LIMB PROSTHESIS PRODUCTION AND MATERIALS THEREFOR

This invention has been conceived and developed primarily in relation to a particular form of limb prosthesis and it is both convenient and appropriate to describe the invention in this particular context. However, it will be appreciated that the invention is equally applicable to other forms of limb prostheses where similar circumstances prevail.

The particular prosthesis in question is the so-called Patella Tendon Borne form which is widely used for below-the-knee amputee patients. The success of such a prosthesis rests heavily on the quality of the fit of a custom made stump cup in the prosthesis into which the limb stump is to be received. Clearly if the cup is too small the prosthesis is unacceptable. Difficulty also arises if, in compensation to avoid undersizing, the cup is too big. This difficulty arises from the fact that it is normally intended for the patient's body weight in the relevant limb to be taken on the patella tendon and the calf but, if the cup is oversized, the stump can sink into the cup to subject the end of the bone to load. This is very painful, as are pressures on the front of the tibia and on the protuberances at the sides of the condyles, and also on areas of tissue overlying major nerves, particularly where those nerves have been severed during surgery.

The usual mode of production with a view to obtaining a good fit for the cup is referred to as the wrap cast technique because it entails first taking an accurate impression of the stump by wrapping a plaster bandage therearound to form a cast. During this wrapping, and while the plaster is setting, the soft tissue of the stump is manipulated by the prosthetist into an acceptable disposition for the purposes of subsequent use of the prosthesis, and this operation is most important in determining the final anatomical shape of the cup. After the cast is set, it is used as a mould in which a replica of the manipulated stump is cast. The cup is then made up on this replica, but only after the replica has been rectified in order that the cup is enlarged relative to the original replica in appropriate areas whereby the bone end and other sensitive parts of the stump will not be subjected to undesirable pressure.

The disadvantage of this technique arises from the fact that the rectification is a lengthy process, typically of about three hours duration, and it is often effected remotely of the patient at a factory rather than by the prosthetist at the hospital or limb fitting centre.

In an alternative mode of production referred to as the pressure casting technique, the prosthetist can both take castings and rectify in the same procedure. In this case clay is built up on the stump in the areas to be relieved from pressure in the cup, and then a complex pressure jacket is applied to the limb and an impression of the stump taken. This technique is time consuming, complicated, user-sensitive, and not in common usage.

An object of the present invention is to ameliorate the difficulties of this situation.

In one aspect of the invention there is provided a method of making a limb prosthesis for an amputee patient which comprises rectifying the limb stump by the application thereto of at least one moulding of viscoelastic material precast to a predetermined shape and then taking an impression of the rectified stump, which impression determines the shape of a stump-receiving cup in said prosthesis.

This aspect of the invention rests on the appreciation that the application of clay in use of the pressure casting technique follows long established rectification principles whereby substantially standard shapes are built up. In the present case the applied material is precast in such a shape rather than built up and it can be selected from a range of sizes for a given shape and/or from a range of different shapes to suit different circumstances.

In another aspect the invention provides an assembly of separate mouldings of viscoelastic material individually precast to a respective predetermined shape for use in the method of the invention.

The material of the invention is to be substantially stable in use, at least to the extent that it does not flow from its appointed position during manipulation by the prosthetist. Also the material should be sufficiently flexible to allow underlying tissue to be manipulated during wrap casting. Preferably in addition the material should adhere well to skin, without causing irritation, or to a suitable protective film material wrapped around the stump, and such adhesion should not break down during wrap casting. At the same time the material should preferably not adhere to, nor inhibit the setting of, plaster bandage or other material used in forming a rectified cast, although difficulty in this respect may be obviated by using an outer protective layer of a suitable film material.

These properties can be met by a variety of materials such as plasticised polyvinylchloride, butyl rubber, natural rubber latex foam and silicone rubber. Any rubber in fact can be used, as can synthetic polymer hydrogels providing that plaster accelerators are also used to prevent setting inhibition.

It has been preferred in development of the invention to date to employ a gel which fulfils all of the above requirements while being additionally advantageous in terms of economy of cost and ease of fabrication.

This last material is made by adding a mixture of plasticiser, dibutyl phthalate, and ethanol to beads of poly(ethylmethacrylate). The result is a liquid which is mobile for about 5 minutes whereafter gelation becomes apparent and is complete in about 20 minutes. The rate of gelation is controllable by way of the alcohol/plasticiser ratio and the molecular weight of the polymer, and the stiffness of the final product material is controllable by way of the polymer/liquid ratio.

In one specific suitable example PEM of molecular weight 40,000 was used as beads of diameter less than 150µm. The related liquid comprised 15% ethanol and 85% phthalate, and the polymer/liquid ratio was 100 ml to 100 g.

Many different plasticisers can be used, as can other methacrylates and related polymers such as acrylates. However, among the methacrylates the methyl form is not suitable.

In production of the proposed assemblies from such material it is preferred that the final mixture be poured, before gelation, into moulds in the form of suitably shaped depressions representing the desired range and formed in spaced but compact distribution in a tray of polythene or other readily formable material from which the mouldings can be peeled for use. The tray is suitably of a stackable form whereby a number thereof can be packaged for storage and/or distribution without the precast shapes being subjected to prolonged force which may cause distortion.

Further clarification of the invention can be gained by consideration of examples of the associated assembly and method described with reference to the accompanying drawings, in which:-

Figures 1, 2 and 3 illustrate, respectively in plan view and related cross-sectional views taken at II-II and III-III, an assembly for use in the production of a patella tendon borne prosthesis, and

Figures 4-9 which schematically illustrate use of the illustrated assembly.

The assembly of Figures 1-3 comprises a tray 10 of suitable material and composed of a rectangular platform 11 having a downwardly turned rim 12 around its periphery. The platform is formed with three dished zones 13-15 in which viscoelastic material of the above-mentioned gel kind is cast up to the top surface level of the platform, the resultant mouldings being denoted respectively 16-18. Th overall depth of the dished zones is no more than half that of the tray rim, and the rim is outwardly stepped at or just below the depth of the zones so that the assembly is stackable with others of like form and with a clearance between the zones, from one tray to the next.

The zones 13-15 involve two different shapes. Zone 13 conforms to a first one of these shapes, which shape is seen in plan as that of a strip having one end portion transversely extended along one side, with the extension preferably being of generally progressively increasing width towards the adjacent strip end. The other shape for zones 14 and 15 is that of an oval disc as seen in plan. Each shape has a cross-sectional shaping which is decreasingly tapered towards its periphery to give a flared form.

Insofar as the mouldings are to be applied to prescribed different areas of the same limb and the proportions of a given limb are generally uniform from one person to another, the mould shapes can have prescribed proportions. The disc shape has length and width in a ratio of about 2:1, while the strip shape has an overall length about 4 times that of the disc, but a similar width to the disc for both the main body of the strip and the extension, and a similar length to the disc for the extension. The mould shapes are all of similar overall thickness of lesser order than the smallest of the above dimensions, with the thickness being in a ratio of about 1:7, say, with the disc width. For use in relation to a leg of an adult the disc mould shape has overall dimensions of about 40x20x3 mm and a range of reduced dimensions can be produced for use in relation to children.

It is to be noted that the strip shape is asymmetric and as illustrated is intended for use in relation to a right leg. Application to a left leg will involve a mirror image shaping.

Also it will be noted that the mould shapes and their proportions are well suited to disposition in a compacted array with the discs effectively nested within the 'angle' of the strip, as shown, and this is advantageous in terms of economy in production of the tray.

As a last comment on the assembly <u>per se</u>, it is preferably covered, after the cast material is cured, with a protective plastics film or other suitable material which is readily peeled off or removed immediately prior to use of the moulds.

Turning to use of the moulds in the fitting procedure for the production of a prosthesis. Figure 4 shows a subject amputated right leg stump 20 and indicates in broken outline the lower end of the femur 21, the patella 22, and the shortened tibia

23. As a first step in the fitting procedur the width of the stump is measured with a suitable instrument at the level of the tibial condyles, the relevant width being indicated by the opposed horizontal arrows in Figure 4.

After this measurement, the stump is closely covered with a thin layer 24 of an appropriate plastics material such as self-adhesive polyester film to extend to above the knee where it is held by an elastic band 25, as shown in Figure 5. The mouldings 16-18 are then located in position, again as shown in Figure 5, on the covered stump where they are retained by natural adhesion. The discs are respectively located over the sides of the tibial condyles, with the disc lengths extending fore-and-aft. The strip moulding is located along the front of the stump over the tibia with the extended strip end lowermost and the extension directed inwardly of the stump. The upper end of the strip is to terminate just below the patella but this may require the strip to be cut to length at such end because the strip moulding length suitably allows for the maximum likely stump length following surgery.

After application of the mouldings a preformed cushioning cap 26 is placed over the lower end of the covered stump as shown in Figure 5, a wet thin sock 27 of knitted or similar form is located over the covered stump, mouldings and cap, and the sock is marked with an indelible pencil to indicate the position and extent of the patella such as by a circle 28, the sock and its marking being indicated in Figure 6.

Following this preparation of the stump, which includes rectification by way of the mouldings, the prepared stump is wrap cast with a plaster bandage 29 as indicated in Figure 6. The stump is held slightly bent at the knee during this operation and the prosthetist manipulates the tissue as during the conventional wrap casting technique.

When this casting and its curing is completed, the wrapped cast 30 is removed by withdrawal from the stump with the knee further bent as indicated by Figure 7, and the cap 26 removed. This cast is then itself used as a mould into which fresh plaster is poured. After curing of the second cast, the first cast is separated by cutting into the same to the depth of the sock where the casts are readily separated. The second cast 31 is exposed with a coarse surface finish and carries with it an adequate amount of the sock marking 28 to indicate the relative position of the patella as shown in Figure 8. This second cast is finished by removing, as appropriate, plaster to enhance the depressed shaping immediately below the patella and also behind the knee where the calf flares inwardly; the surface is smoothed overall; and it is checked in respect of its condylar width as shown by arrows again. The resultant replica 32 of the rectified stump is thereafter used in a conventional manner in the production of the cup in an artificial limb for the stump.

While the invention has been described with more specific reference to the drawings, this is by way of example and variation of the invention is possible within the scope of the appended claims. For example, application of the invention in relation to other forms of prosthesis than the patella tendon borne form, and also to limbs other than the leg, is possible as noted earlier. In addition to a set of mouldings of effectively standard shaping which will inevitably be applied in relation to a given prosthesis, one or more mouldings, suitably of relatively small disc and/or other shape, can be included in the assembly for location over sensitive areas of the stump detected during palpation by the prosthetist and individual to a particular patient. Also as noted earlier various materials are suitable for the precast moldings. The stump covering can be of various materials compatible with the skin and mouldings and it can be presented in the form of a bag or a protective film sheet such as of the widely available pvc self-adhesive type. The sock facilitates demarcation and separation of the two casts and is suitably of knitted synthetic fibre material. The cap is a conventional item of commercially available form, typically of coarse skeleton polyester foam material. Lastly, plaster is clearly an appropriate material for the casts for reason of its well-established suitability for such purposes, but alternatives can be used if desired.

Claims

1. A method of making a limb prosthesis for an amputee patient which comprises rectifying the relevant amputated limb stump by the application thereto of at least one moulding of viscoelastic material precast to a predetermined shape, taking an impression of the rectified stump, and using the impression to determine the shape of a stump-receiving cup in said prosthesis.

2. A method according to Claim 1 wherein, before rectification, said stump is closely covered with a thin layer of protective material readily removed therefrom, and each said moulding is adhered to said layer.

3. A method according to Claim 1 or 2 wherein said impression is taken by wrapping-casting material in bandage form around said rectified stump and thereafter removing th resultant wrapped cast when set.

4. A method according to Claim 3 wherein said socket shape is determined from said impr ssion by pouring further casting material into said

wrapped cast to form a replica of said rectified stump, removing said cast to expose said replica when set, and forming said socket on said replica.

5. A method according to Claim 4 wherein said bandage form and further casting materials each comprise plaster, and said rectified stump is covered with a sock of material which becomes bonded and removable with said wrapped cast subsequently to demark the same from said replica.

6. A method according to Claim 5 wherein a positional reference marking for said stump is applied to said sock which marking is incorporated into said wrapped cast and thereafter conveyed, at least in part, to said replica.

7. A method according to any preceding claim for making a leg prosthesis of patella borne form for a below-the-knee amputee patient, wherein said rectifying comprises applying one said moulding of disc shape over one side of the condylar protuberances, applying a similar moulding over the other side of said protuberances, and applying a further said moulding of strip shape longitudinally over the front of the tibia.

8. A method according to Claim 7 wherein, at the same time as said rectifying and before application of said sock, a cap of cushioning material is located over the free end of said stump.

9. For use in accordance with the method according to any preceding claim, an assembly of separate mouldings of viscoelastic material individually precast to a respective predetermined shape.

10. An assembly according to Claim 9 wherein said mouldings are releasably formed in respective dished zones of a common support.

11. An assembly according to Claim 10 wherein said support is stackable with other assemblies of like form.

12. An assembly according to Claim 9,10 or 11 for use in a method according to Claim 7 or 8, comprising three said mouldings including two of like oval disc shape in plan, and another of strip shape in plan having one end portion transversely extended along one side, each such shape being of decreasingly tapered flared form towards its periphery in cross-section.

13. An assembly according to Claim 12 wherein said transverse extension is of generally progressively increasing width towards the free end of said one end portion.

14. An assembly according to Claim 12 or 13 wherein said disc shape has its overall length and width in a ratio of about 2:1; said strip shape has an overall length about 4 times that of said disc, but an overall width for each of the main body of said strip and said extension similar to that for said disc, and a similar overall length for said extension to said disc; and each said shape has an overall thickness in a ratio of about 1:7 with said disc width.

15. An assembly according to Claim 14 wherein said disc shape has overall dimensions of about 40x20x3 mm.

16. An assembly according to any one of Claims 12-15 wherein said three mouldings are mutually disposed in a nested array with said disc shapes located alongside successive portions of the main body of said strip shape in the angle formed between such body and the associated extension.

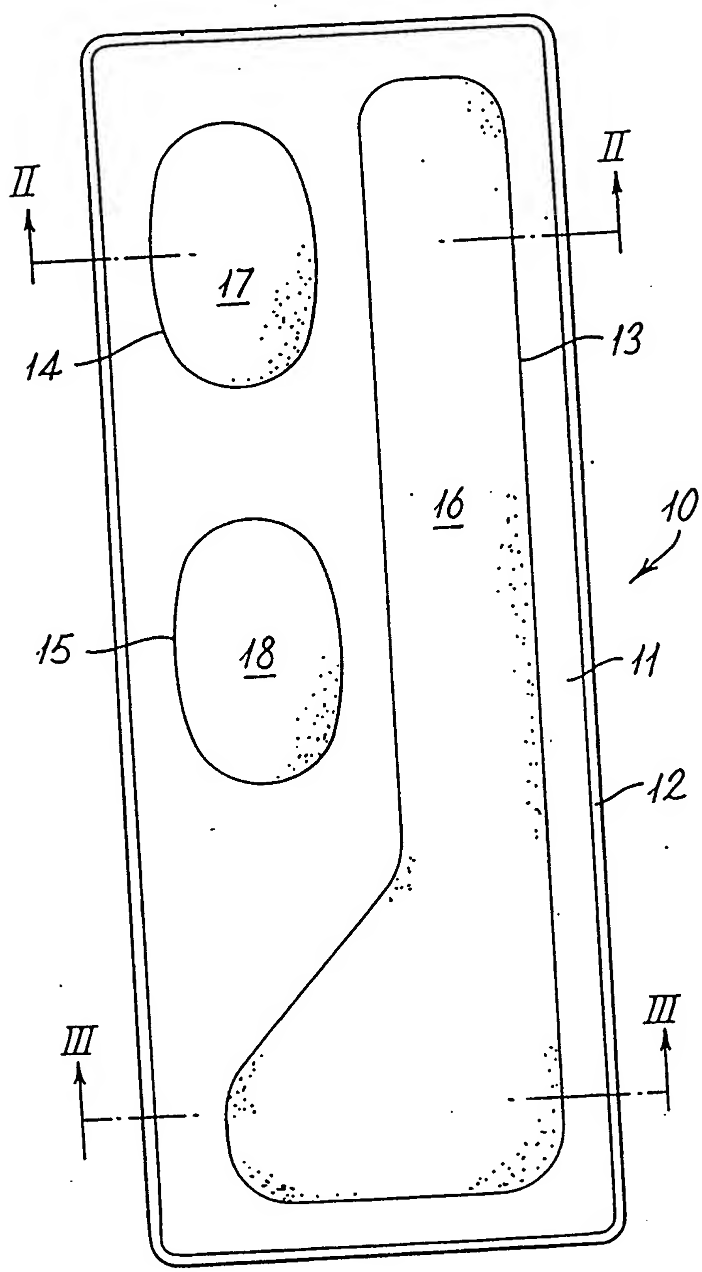

Fig. 1

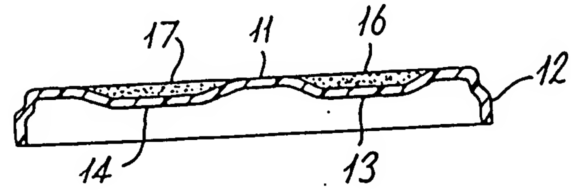

Fig. 2

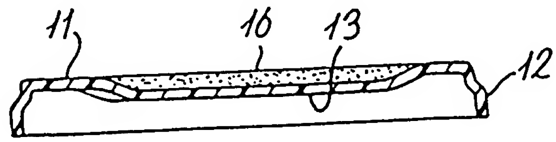

Fig. 3

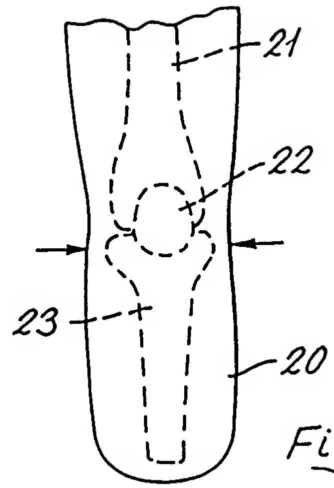

Fig. 4

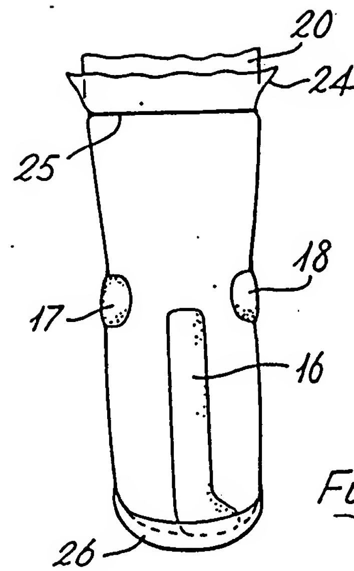

Fig. 5

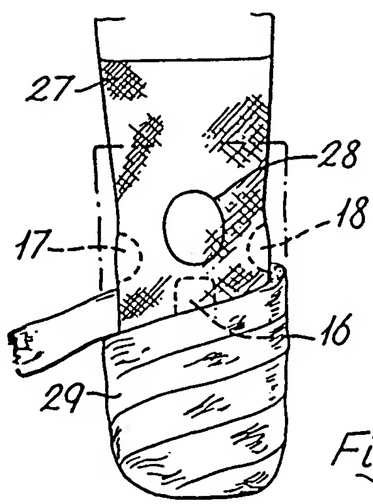

Fig. 6

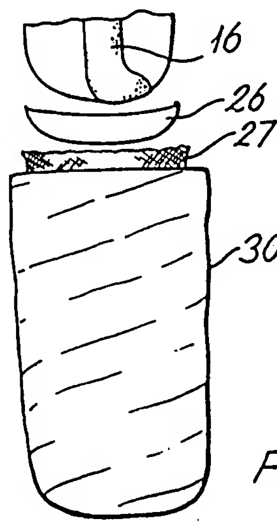

Fig. 7

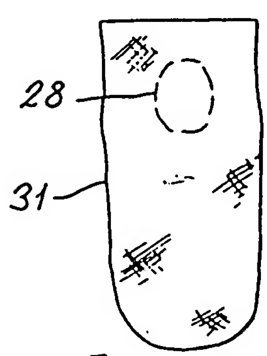

Fig. 8

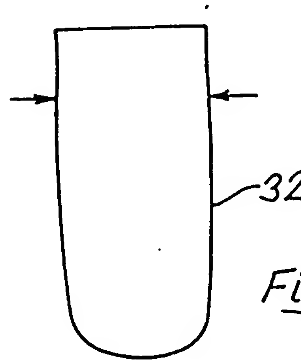

Fig. 9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 87 30 8274

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US-A-3 393 407 (E.J. KANDEL) * Figures 1-3 * ---	1	A 61 F 2/80
A	US-A-2 424 278 (P.W. KUNKEL) * Figures 1-4 * ---	1	
A	US-A-2 664 572 (E. BLEVENS) * Figures 1-3 * ---	1	
A	COMPUTER SYSTEMS, vol. 6, no. 10, October 1986, pages 15,16, Bromley, GB; "Shape a leg" -----	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	11-12-1987	ARGENTINI A.

CATEGORY OF CITED DOCUMENTS

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